

5

**Handheld device for analysis with a conveyance
path for test elements**

10

The present invention relates to a handheld analysis device for analyzing a sample, in particular a biological liquid, for a medically significant component, comprising an analysis sensor to which an analytic consumable may be supplied along a conveyance path, a display unit, and a housing, which has a housing opening for an analytic consumable, the conveyance path leading to the housing opening.

15

Carriers for rapid tests have become established for chemical and biochemical analysis of solid and liquid sample materials in laboratories specialized for this purpose and, in particular, also for use outside stationary laboratories. Such carrier-bound rapid tests may be performed easily and straightforwardly even by laymen despite the often

20 complex reactions involving sensitive reagents.

25

Test elements for determining the blood glucose level of diabetics are a known example of carrier-bound rapid tests. Diagnostic test elements provided in the form of strips are also called to as test strips. Known embodiments thereof include, for

example, single-field or multiple-field test strips for urine analysis and various indicator papers. Since various forms of test elements other than test strips exist, test elements are more generally denoted as "analytic consumables", which also include lancets or sample removal elements, for example.

30

Analytic consumables of this type are used in a portable handheld analysis device which analyzes a coloration of a test strip photometrically using an optical

analysis sensor, for example. The analytic consumables may be stored in a drum magazine, as is described, for example, in EP 1 022 565 A2. The drum magazine described therein comprises multiple chambers arranged annularly, which can contain analytic consumables. Each chamber has a removal opening on a front face of the drum magazine. These removal openings are typically sealed by sealing foil, in order to protect the analytic consumables from detrimental environmental influences, such as moisture, light, or dust.

Handheld analysis devices for analyzing a medically significant component of a sample, such as devices for blood glucose monitoring, are typically used multiple times a day and carried continuously by a user. Therefore, there is a need to provide such handheld analysis devices as small as possible and simultaneously make them as easy to handle as possible.

This object is met according to the present invention by a handheld analysis device of the above mentioned type in that it has a drivable conveyance roll, by which a consumable protruding into the conveyance path may be gripped and moved along the conveyance path.

In a handheld analysis device according to the present invention an analytic consumable, to which a drop of blood or urine was applied, for example, may be supplied by means of the conveyance roll to the analysis sensor in the interior of the device much more easily with the required positioning precision than is the case in handheld analysis devices according to the prior art.

The handheld analysis device preferably has a switch which is actuated upon insertion of a consumable into the housing opening and turns on a drive of the conveyance roll. Such a switch may be a mechanical switch, for example, which is triggered by a small rotational movement of the conveyance roll, which is caused by pressure of an inserted consumable against the conveyance roll. The switch may be implemented as a light barrier, for example. A further possibility is to implement the

switch as two contact fields which are arranged at a distance from one another and brought into electrical contact by a consumable inserted into the conveyance opening. Even a very slight change of the electrical resistance between the two contact fields, as is caused by an inserted consumable made of plastic or paper, for example, may be reliably detected by a suitable transistor circuit.

In a handheld analysis device according to the present invention, the user only has to insert one end of the consumable lightly into the housing opening. The conveyance roll then grips the consumable. The transport of the consumable and its correct positioning with respect to the analysis sensor is performed automatically. A final position of the consumable may be detected mechanically, electrochemically, or optically using a position switch, which then turns off the drive of the conveyance roll. The measure according to the present invention also has the advantage that the removal facility may be implemented compactly. Hence, a handheld analysis device may be made smaller than in the prior art, especially if a drum magazine is used. Known handheld analysis devices having a removal facility for a drum magazine according to EP 1 022 565 A2 require a pushrod of significant length implemented as a plunger, which is inserted for removal of a consumable into an insertion opening of a chamber of the drum magazine. The insertion opening is diametrically opposite of a removal opening. Thus a consumable contained in the chamber is pushed out of the chamber and a housing opening of the device. For a pushrod to fulfill this purpose, it must have a length which at least corresponds to the length of the path on which a consumable is transported upon removal. In order to house this pushrod, such a handheld analysis device according to the prior art must therefore have a significant length, which is at least the sum of the lengths of the pushrod and the drum magazine.

An advantage of the present invention is that the pushrod and therefore also the housing of a handheld analysis device may be significantly shortened. In a handheld analysis device according to the present invention it is already sufficient if a consumable can be pushed by a pushrod so far out of the chamber that it may be gripped by the conveyance roll and moved in the removal direction. The conveyance roll is preferably

situated directly adjacent to the removal opening of the inserted drum magazine, so that it is sufficient if the consumable is pushed approximately 0.5 to 1 cm out of its chamber by the pushrod. For this purpose, a pushrod having a length of 1 to 2 cm is already sufficient, so that a handheld analysis device according to the present invention may be approximately 10 cm shorter than a device according to the prior art.

Using the conveyance roll, a consumable may advantageously be pushed without difficulty far enough out of a housing opening of the housing so that a sample, such as a drop of blood, may be applied to the consumable without a risk of contamination of the handheld analysis device by the sample. A handheld analysis device according to the present invention may be used much more comfortably and may be handled more easily due to this alleviation of the application of a sample to an analytic consumable. In known handheld analysis devices a longer pushrod is required the further the consumable is to be pushed out of the housing opening of the handheld analysis device. Hence, in known handheld analysis devices, easier handling during application of a sample to a consumable is always connected with the disadvantage of larger dimensions of the handheld analysis device.

Further details and advantages of the present invention will be explained on the basis of exemplary embodiments with reference to the attached figures. Identical and corresponding parts are identified by identical reference numerals. The special features shown therein may be used individually or in combination to provide preferred embodiments of the present invention. In the Figures:

Figure 1 shows an embodiment of a handheld analysis device,

Figure 2 shows an embodiment of a removal facility of the handheld analysis device shown,

Figures 3 through 7 show a further exemplary embodiment of a removal facility during removal of a consumable, and

Figures 8 through 14 show a further exemplary embodiment of a handheld analysis device during insertion of a consumable.

5 Figure 1 shows a compact, portable handheld analysis device 1 for analyzing a sample, particularly a biological liquid, for a medically significant component such as blood, urine or saliva. The handheld analysis device 1 shown in Figure 1 is used for determining the concentration of glucose in blood and has a power source 2 in the form of commercially available batteries or solar cells. The result of an analysis is displayed
10 by a display unit 3, preferably a liquid crystal display. The handheld analysis device 1 comprises a housing 4, which has a loading opening 5 for receiving a replaceable drum magazine 6 in a magazine compartment 7. The drum magazine 6 is rotatable in the magazine compartment 7 step-by-step around its geometrical longitudinal axis by an electric motor 8, so that analytic consumables 9 stored in the drum magazine 6 may be
15 removed through a housing opening 10 of the housing 4.

The generally cylindrical drum magazine 6 has multiple chambers 11 that are disposed in a ring-shaped arrangement around its geometrical longitudinal axis and can contain analytic consumables 9. The number of chambers 11 may be varied arbitrarily
20 to a large extent. Typically, 10 to 100 chambers 11 are expedient, 15 to 30 chambers 11 are preferably provided. Each of the chambers 11 has a removal opening 12 on a front face of the drum magazine 6 for removing a consumable 9 and an insertion opening 13 diametrically opposite the removal opening 12 for inserting a plunger 14 of a removal facility 29. The insertion openings 12 and the removal openings 13 are sealed
25 by a sealing foil to protect the consumables 9 from detrimental environmental influences. As described in EP 1 022 565 A2, consumables 9 to be used may be pushed out of the chambers 11 by the pushrod 14 implemented as a plunger. The sealing foil of the insertion opening 13 is thereby penetrated by the plunger 14 and the sealing foil of the removal opening 12 penetrated by the consumable 9.

The consumables 9 are preferably test strips, to which a sample may be applied. A reagent contained in the test strips reacts with a medically significant component of the sample, so that the result of the reaction may be analyzed using an analysis sensor 15 of the handheld analysis device 1. Such an analysis sensor 15 may be an optical sensor, for example, which detects a color change of a consumable 9 provided as a test strip, or it may be an electrical sensor which detects a conductivity change of the sample.

The drum magazine 6 may be rotated step-by-step by the electric motor 8, so that one after another each of the removal openings 12 can be aligned with the housing opening 10 of the housing 4 and then a consumable 9 pushed out of the chamber 11, which is currently positioned for removal, by the plunger 14 of the removal facility 29. A special feature of the embodiment shown is that the removal facility 29 comprises a drivable conveyance roll 16, shown in Figure 2, in addition to the plunger 14. The conveyance roll 16 may grip a consumable 9 protruding out of the drum magazine 6 and move it entirely or partially out of the drum magazine in the removal direction. The conveyance roll 16 therefore allows the plunger 14 to be much shorter than in devices known in the prior art, since it is sufficient if the consumable 9 may be pushed a small amount out of the chamber 11 by the plunger 14.

The conveyance roll 16 is preferably situated directly adjacent to the removal opening 12 of the inserted drum magazine 6. In this way a consumable 9 has to protrude only as little as possible out of its chamber 11 to be able to be gripped by the conveyance roll 16. In this way only a small minimum distance of approximately 1 mm is required between the front face of the inserted drum magazine 6 and the conveyance roll 16, so that the conveyance roll 16 and the inserted drum magazine 6 may rotate undisturbed. As a further measure for gripping a consumable 9 as close as possible to the removal opening 12 by the conveyance roll 16 and thus for making the plunger 14 as short as possible, the conveyance roll 16 preferably has a small diameter of approximately 3 to 10 mm, especially preferably of 4 to 7 mm.

The conveyance roll 16 and a conveyance surface, which is stationary in relation thereto, form together a conveyance gap, through which the consumable 9 is moved in the conveyance direction. Alternatively, the conveyance roll 16 may - as shown in Figures 3 to 7 - form a conveyance gap together with a counter roll 31 situated diametrically opposite thereto. The conveyance gap preferably has a profile tailored to the consumable 9, in the form of a groove in the conveyance surface or the counter roll, for example, so that a test field of the consumable 9 is not squeezed and thus impaired during removal. The embodiment shown in Figure 2, in which the conveyance roll 16 works together with a stationary conveyance surface, offers the advantage that the removal facility 29 requires fewer movable parts and thus may be manufactured especially cost-effectively and is less susceptible to breakdown.

The handheld analysis device 1 has a conveyance base 17 extending in the removal direction to support a removed consumable 9. The conveyance surface, which forms the conveyance gap 33 together with the conveyance roll 16, is part of the conveyance base 17 extending from the magazine compartment 7 to the housing opening 10. In this way, a removed consumable 9 is supported and guided on its entire conveyance path by the conveyance base 17.

A further conveyance roll 18, which forms a second conveyance gap together with the conveyance base 17, is situated at a distance from the conveyance roll 16 in the conveyance direction. While the first conveyance roll 16 is arranged as close as possible to the removal opening 12 of an inserted drum magazine 6 so that a consumable 9 has to protrude as little as possible out of its chamber 11 to be able to be gripped, the second conveyance roll 18 is situated as close as possible to the housing opening 10 of the housing 4, so that a consumable 9 may be pushed as far as possible out of the housing opening 10 of the housing 4. The further a consumable 9, e.g. in the form of a test strip, may be pushed out of the housing opening 10 of the housing 4, the easier may a sample, such as a drop of blood, be applied to the consumable 9 without contaminating the housing 4.

The conveyance base 17 is provided with a groove 19 running in the conveyance direction. This advantageously minimizes friction between the consumable 9 and the conveyance base 17. While the conveyance base 17 is manufactured from a material which is as smooth as possible, having a low coefficient of friction, such as polycarbonate, the conveyance rolls 16, 18 preferably have a surface implemented to increase friction, having the largest possible coefficient of friction. For example, the rolls may have a roughened surface, may be made of hard or soft rubber, or may be coated with a rubber-like plastic to increase the friction. If the consumable 9 has a thickness varying over its length, the conveyance roll may be spring-loaded to adapt to differences in thickness.

In the embodiment shown, the conveyance rolls 16, 18 and the plunger 14 of the removal facility 29 are moved by a single drive 30. Alternatively, it is also possible to provide separate micromotors as drives for the plunger 14 and the conveyance rolls 16, 18 or even for each of the conveyance rolls 16, 18. However, it is more cost-effective and therefore preferable if the removal facility 29 only has one drive 30, which drives both the conveyance rolls 16, 18 and also the plunger 14.

In order to be able to transmit movement generated by the joint drive 30 of the removal facility 29 both to the plunger 14 and the conveyance rolls 16, 18, the removal facility 29 comprises a threaded rod 20 having a thread 21. The rod 20 extends laterally along the inserted drum magazine 6 and projects on both sides beyond its front faces. In the embodiment shown in Figure 2, the removal facility 29 has a transmission 22, via which an electric motor belonging to the drive 30 may move the plunger 14. The threaded rod 20 comprises a gearwheel 23 which works together with the transmission 22, so that the threaded rod 20 may be set into rotation via the transmission 22 and the gearwheel 23. The gearwheel 23 may be a separate component which is attached to the threaded rod 20, or may be integrated in the threaded rod 20, by providing a section of the threaded rod 20 with teeth, for example. In order to be able to provide the threaded rod 20 as short as possible, the gearwheel 23 is preferably situated on or near

an end of the threaded rod 20 and the thread 21 is preferably situated on or near the other end.

A rotation of the threaded rod 20 is transmittable to the conveyance rolls 16, 18 via the external thread 21 situated on the other end of the threaded rod 20. For this purpose, each of the two conveyance rolls 16, 18 is provided with a shaft 24 which carries a gearwheel 25 which engages in the thread 21 of the threaded rod 20. The shaft 24 and the threaded rod 20 are mounted using bearing rings 26, which lie rotatably with little frictional resistance in fitted recesses 27 of the carrier 28.

The conveyance rolls 16, 18 are preferably drivable around their geometrical longitudinal axes both clockwise and also counterclockwise in order to be able to move a consumable 9 both in the removal direction and also in the opposite direction. This measure allows a consumable 9, such as a test strip, to be pushed as far as possible out of the opening 10 of the housing 4, in order to facilitate applying a sample, and to subsequently retract the consumable 9 back into the handheld analysis device 1. It is thus possible to situate the analysis sensor 15 at a protected location in the interior of the housing 4, where interfering environmental influences, such as stray light, are minimized. The analysis sensor 15 is preferably situated between the two conveyance rolls 16, 18, in particular on the side of the conveyance base 17 diametrically opposite of the conveyance rolls 16, 18. The conveyance base 17 is provided with a recess between the two conveyance rolls 16, 18, so that the analysis sensor 15 may detect a sample applied to a consumable 9. The groove 19 of the conveyance base 17 running in the conveyance direction has its width and depth dimensioned in such a manner that a sample applied to the consumable 9 does not come into contact with the conveyance base 17.

If the conveyance rolls 16, 18 are rotatable around their geometrical longitudinal axes both clockwise and also counterclockwise, so that the consumable 9 may be moved both in the removal direction and also in the opposite direction, it is advantageously possible to reinsert a used consumable 9 into its chamber 11 of the

drum magazine 6 after analysis is completed. In order to facilitate returning of a used consumable 9 to the magazine, the plunger 14 is equipped with a gripper element which may operationally engage a consumable 9 and allows a consumable 9 to be pulled by the plunger 14 as well. For example, the gripper element may comprises an
5 electromagnet which attracts an iron part of the consumable, or a mechanical hook which turns over at a predefined tensile force, as is exerted by the conveyance rolls 16, and releases the consumable 9.

In this way all consumables 9 contained in a drum magazine 6 may
10 advantageously be disposed of together and a user no longer needs to dispose of a used consumable 9 individually after each analysis.

Figures 3 through 7 show a schematic illustration of a further exemplary embodiment of a removal facility during removal of a consumable 9 from a drum
15 magazine 6. In contrast to the embodiment described above, in the removal facility 29 shown in Figures 3 through 7, the conveyance gap 33 is not provided by the conveyance rolls 16 and a conveyance surface stationary in relation thereto, but rather by the conveyance roll 16 and a counter roll 31 situated diametrically opposite thereto. In the embodiment shown in Figures 3 through 7, both the conveyance roll 16 and also
20 the counter roll 31 may each be implemented as drivable. However, it is sufficient if only the conveyance roll 16 is drivable. For the counter roll 31, it is sufficient if it is mounted in a rotatable way, so that it may be set into rotation by a consumable 9 passing through the conveyance gap 33.

In the embodiment shown in Figures 3 through 7, the consumables 9 are test
25 strips which have a test field 32 for receiving a sample. To prevent impairment of the test field 32 during removal of the consumable 9 from the drum magazine 6 and to prevent contamination of the removal facility 29, particularly the conveyance roll 16 and the counter roll 31, by the consumable 9, the consumable 9 passes through the
30 conveyance gap in such a manner that the test field 32 of the consumable 9 extends transversely to the geometric axis of rotation of the conveyance roll 16 in the

embodiment shown. In this way, the danger of impairing the test field 32 of the consumable 9 is reduced even further than may be achieved in the embodiment, which was described on the basis of Figure 2, by a conveyance gap 33 having a profile, which is tailored to the consumable 9 and has the form of a groove 19 in the conveyance base 17 providing the conveyance surface, for example.

Figure 3 shows the drum magazine 6 and a consumable 9 contained therein together with the removal facility 29 in the starting position. As may be seen in Figure 4, the consumable 9 is pushed out of the drum magazine 6 by the plunger 14 and gripped by the conveyance roll 16 as soon as it protrudes into the conveyance gap 33 between the conveyance roll 16 and the counter roll 31. Figure 5 shows how the consumable 9 is pushed out of the housing opening 10 of the handheld analysis device 1 by the conveyance roll 16, so that a sample, such as a drop of blood, may be applied to a sample application surface 34, from which it reaches the test field 32. Subsequently, as shown in Figure 6, the consumable 9 is retracted back into the handheld analysis device 1 by the conveyance roll 16, which now rotates in the opposite direction, so that the test field 32 is positioned in front of the analysis sensor 15 for the analysis of the sample. After the plunger 14 has pushed the consumable 9 out of the drum magazine 6, it returns into its starting position shown in Figure 6. After completion of the analysis, the consumable 9 is moved back in the removal direction by the conveyance roll 16 and ejected from the handheld analysis device 1, as shown in Figure 7.

Figures 8 through 14 show a further embodiment of a handheld analysis device 1 during insertion of a consumable 9. This handheld analysis device 1 differs from the handheld analysis device 1 described above essentially in that it does not have a loading opening for receiving a replaceable drum magazine. In the handheld analysis device 1 shown in Figures 8 through 14, analytic consumables 9 in the form of test strips are therefore supplied to the device externally through the housing opening 10. By insertion of a consumable 9 into the housing opening 10, a microswitch (not shown) is actuated, through which a drive of the conveyance roll 16 and the counter roll 31 is turned on. As shown in Figure 9, the consumable 9 is then gripped by the conveyance

roll 16 and the counter roll 31 and drawn along the conveyance path into the device interior.

If the analytic consumables 9, as in the embodiment shown, are not removed
5 from a drum magazine 6 loaded into the handheld analysis device 1, but rather supplied externally, there is increased danger that the consumables 9 have been spoiled by aging or detrimental environmental influences, such as light, moisture, or dust. A consumable 9 is therefore first conveyed from the insertion position shown in Figure 10 into the test position shown in Figure 11, in which it is checked whether it is spoiled.
10 This is done by an optical measuring unit, by which a film white level of the consumable 9 is determined. For this purpose a consumable 9 provided as a test strip has a section having a white plastic film, which discolors with increasing age and moisture absorption and may be arranged in the area of the test field 32, for example. By determining the film white level, it may be established whether the inserted consumable 9 is spoiled. If a
15 consumable 9 is spoiled, it is ejected from the handheld analysis device 1 using the conveyance roll 16 and the counter roll 31. If the consumable 9 is still functional, it is brought by the conveyance roll 16 and the counter roll 31 along the conveyance path into the sample application position shown in Figure 14. In the sample application position, one end of the consumable 9 protrudes out of the housing opening 10, so that
20 a sample, such as a blood drop, may be applied to the sample application surface 34.

An important advantage of the handheld analysis device 1 described is that the consumable 9 may protrude far enough out of the housing opening 10 in the sample application position shown in Figure 14 that a sample may be applied easily to the
25 sample application surface 34 without thereby contaminating the handheld analysis device 1. A consumable 9 protruding relatively far out of the housing opening 10 in the sample application position, reveals more easily to a user that a sample is now to be applied to the sample application surface 34. In particular, the test field 32, to which the sample is supplied by capillary forces, for example, may be situated so close to the
30 sample application surface 34 that the required sample volume is minimal.

List of reference numbers

- 1 handheld analysis device
- 2 power source
- 3 display unit
- 4 housing
- 5 loading opening
- 6 drum magazine
- 7 magazine compartment
- 8 electric motor
- 9 consumable
- 10 housing opening
- 11 chamber
- 12 removal opening
- 13 insertion opening
- 14 pushrod
- 15 analysis sensor
- 16 conveyance roll
- 17 conveyance web
- 18 conveyance roll
- 19 groove
- 20 threaded rod
- 21 thread
- 22 transmission
- 23 gearwheel
- 24 shaft
- 25 gearwheel
- 26 bearing ring
- 27 recess
- 28 carrier
- 29 removal facility

- 30 drive
- 31 counter roll
- 32 test field
- 33 conveyance gap
- 34 sample application surface